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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Prospective Grant of an Exclusive Patent License: The Development of a CD276 Antibody-Drug Conjugate (ADC) for the Treatment of Solid Tumors

AGENCY: National Institutes of Health, HHS.

ACTION: Notice.

SUMMARY: The National Cancer Institute, an institute of the National Institutes of Health, Department of Health and Human Services, is contemplating the grant of an Exclusive Patent License to practice the inventions embodied in the Patents and Patent Applications listed in the Supplementary Information section of this notice to BrickBio, Inc. ("BrickBio") located in Woburn, Massachusetts.

DATES: Only written comments and/or applications for a license which are received by the National Cancer Institute's Technology Transfer Center on or before [INSERT DATE 15 DAYS FROM DATE OF PUBLICATION OF NOTICE IN THE FEDERAL REGISTER] will be considered.

ADDRESSES: Requests for copies of the patent application, inquiries, and comments relating to the contemplated an Exclusive Patent License should be directed to: Rose M. Freel, Ph.D., Senior Licensing and Patenting Manager, Telephone: (301) 624-8775; E-mail: rose.freel@nih.gov.

SUPPLEMENTARY INFORMATION:

Intellectual Property

United States Provisional Patent Application No. 62/051,650, filed September 17, 2014 and entitled "Anti-CD276 Polypeptides and Proteins" [HHS Reference No. E-250-2014-0-US-01]; PCT Patent Application PCT/US2015/050365, filed September 16, 2015 and entitled "Anti-CD276 Polypeptides and Proteins" [HHS Reference No. E-250-2014-0-

PCT-02]; Canadian Patent Application No. 2961609, filed September 16, 2015 and entitled “Anti-CD276 Polypeptides and Proteins” [HHS Reference No. E-250-2014-0-CA-03]; United States Patent No. 10,604,582, filed March 16, 2017 and entitled “Anti-CD276 Polypeptides and Proteins” [HHS Reference No. E-250-2014-0-US-04]; Japanese Patent No. 6613304, filed September 16, 2015 and entitled “Anti-CD276 Polypeptides and Proteins” [HHS Reference No. E-250-2014-0-JP-05]; Japanese Patent No. 6734227, filed May 25, 2017 and entitled “Anti-CD276 Polypeptides and Proteins” [HHS Reference No. E-250-2014-JP-07]; European Patent No. 3193933, filed September 16, 2015 and entitled “Anti-CD276 Polypeptides and Proteins” [HHS Reference No. E-250-2014-0-EP-06] and as validated in Germany, Spain, France, UK, and Italy; and US Patent Application No. 16/812,980, filed March 9, 2020 [HHS Reference No. E-250-2014-0-US-08]; and

United States Provisional Patent Application 62/947,135, filed December 12, 2019, and entitled “ANTIBODY-DRUG CONJUGATES SPECIFIC FOR CD276 AND USES THEREOF” [HHS Reference No. E-145-2019-0-US-01]; PCT Application No. PCT/US2020/063732, filed December 8, 2020, and entitled “ANTIBODY-DRUG CONJUGATES SPECIFIC FOR CD276 AND USES THEREOF” [HHS Reference No. E-145-2019-0-PCT-02]; Australian Application No. 2020402752, filed December 8, 2020, and entitled “ANTIBODY-DRUG CONJUGATES SPECIFIC FOR CD276 AND USES THEREOF” [HHS Reference No. E-145-2019-0-AU-03]; Canadian Application No. 3161573, filed December 8, 2020, and entitled “ANTIBODY-DRUG CONJUGATES SPECIFIC FOR CD276 AND USES THEREOF” [HHS Reference No. E-145-2019-0-CA-04]; European Application No. 20834060.4, filed December 8, 2020, and entitled “ANTIBODY-DRUG CONJUGATES SPECIFIC FOR CD276 AND USES THEREOF’ [HHS Reference No. E-145-2019-0-EP-05]; Japanese Application No. 2022-535127, filed December 8, 2020 [HHS Reference No. E-145-2019-0-JP-06]; US Patent

Application No. 17/783,171, filed June 7, 2022 [HHS Reference No. E-145-2019-0-US-07];

and all U.S. and foreign patent applications claiming priority to the aforementioned applications for each technology.

The patent rights in these inventions have been assigned and/or exclusively licensed to the government of the United States of America.

The prospective exclusive license territory may be worldwide and the field of use may be limited to: “The use, development, manufacturing and commercialization of an antibody-drug conjugate (ADC) with single antigen specificity comprising:

(1) The CDR sequences of the m8524/m276 monoclonal antibody;

(2) a cleavable or non-cleavable linker; and

(3) a payload selected from the following categories: pyrrolobenzodiazepine (PBD), maytansinoid, auristatin, camptothecian, TLR agonist, STING agonist, cytokine or cytokine mimetic, targeted protein degrader, or oligonucleotide; for the treatment of CD276-expressing solid tumors.

The licensed field of use specifically excludes any (a) non-specified immunoconjugates, including, but not limited to, chimeric antigen receptors (CARs) and variants thereof, (b) unconjugated antibodies, (c) bispecific antibodies, and (d) antibody-radioligand conjugates.”

CD276, also known as B7-H3, is a cell surface tumor endothelial marker that is highly expressed in the tumor vessels of human lung, breast, colon, endometrial, renal, and ovarian cancer, but not in the angiogenic vessels of healthy tissue. This differential expression makes CD276 an attractive target for cancer treatment due to the ability to selectively target pathological angiogenesis without impacting physiological

angiogenesis. The E-250-2014 technology discloses antibodies that bind selectively to CD276 and other antibody-based therapeutic formats such as antibody drug conjugates (ADCs). The E-145-2019 technology discloses an ADC based on a modified version of the m276/m8524 antibody that is disclosed under E-250-2014 that incorporates mutations for site-directed conjugation and disruption of Fc receptor binding.

This notice is made in accordance with 35 U.S.C. 209 and 37 CFR part 404. The prospective exclusive license will be royalty bearing, and the prospective exclusive license may be granted unless within fifteen (15) days from the date of this published notice, the National Cancer Institute receives written evidence and argument that establishes that the grant of the license would not be consistent with the requirements of 35 U.S.C. 209 and 37 CFR part 404.

In response to this Notice, the public may file comments or objections. Comments and objections, other than those in the form of a license application, will not be treated confidentially, and may be made publicly available.

License applications submitted in response to this Notice will be presumed to contain business confidential information and any release of information in these license applications will be made only as required and upon a request under the Freedom of Information Act, 5 USC 552.

Dated: February 27, 2023.

Richard U. Rodriguez,

Associate Director,

Technology Transfer Center,

National Cancer Institute.

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